



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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| <p>(51) International Patent Classification <sup>6</sup> :<br/><b>A61F 2/16</b></p>   | <p><b>A1</b></p> | <p>(11) International Publication Number: <b>WO 98/05273</b><br/>(43) International Publication Date: 12 February 1998 (12.02.98)</p>   |
| <p>(21) International Application Number: PCT/US97/13209<br/>(22) International Filing Date: 25 July 1997 (25.07.97)<br/>(30) Priority Data:<br/>08/692,566 6 August 1996 (06.08.96) US<br/>(71) Applicant: CHIRON VISION CORPORATION [US/US]; 555 West Arrow Highway, Claremont, CA 91711 (US).<br/>(72) Inventors: KANNER, Lauren, L.; 1161 Smoketree Lane, Santa Ana, CA 92705 (US). FUNSTEN, Robert, C.; 21682 Impala Lane, Huntington Beach, CA 92646 (US).<br/>(74) Agents: KRIEGER, Paul, E. et al.; Pravel, Hewitt, Kimball &amp; Krieger, P.C., 10th floor, 1177 West Loop South, Houston, TX 77027-9095 (US).</p>   |                  | <p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b><br/>With international search report.</p> |
| <p>(54) Title: FOLDABLE INTRAOCULAR LENS</p> <p>(57) Abstract</p> <p>This invention is a foldable intraocular lens (2) for insertion into the posterior chamber of the eye having support members (6, 8) extending from the optic (4) to be securely received within the ciliary sulcus or capsular bag of the eye. One of the support members (8) includes an anchor hole (22) to promote tissue ingrowth to enhance long term fixation. The other support member (6) includes a deflectable spring haptic (16) disposed therein, whereby the spring haptic may cooperate with the ciliary sulcus for stabilization of the lens on implantation in the ciliary sulcus, or be deflected when the lens is implanted into the capsular bag.</p> |                  |   |

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### FOLDABLE INTRAOCULAR LENS

The present invention relates to an artificial lens for implantation into an eye, either in the replacement of the natural, crystalline lens (i. e., an aphakic application) or as a corrective supplement to the natural lens (i. e., a phakic application).

The human eye is subject to a variety of diseases and disorders. It is not uncommon after trauma to the eye, surgery to correct some ocular disfunction or even as a consequence of advanced age, that the crystalline lens of the eye becomes disfunctional, whether from development of a cataract, injury or other impairment. It has become common to surgically remove the afflicted lens and to replace it with an artificial intraocular lens. In cases of refractive errors, the focal point may fall significantly short of (myopia) or beyond (hyperopia) the retina. In such conditions the implanted artificial lens supplements the function of or replaces the natural lens and may be a substitute for contact lenses or spectacles.

Intraocular lenses differ significantly in structure, design, material and placement within the eye. Surgical procedures employed to implant the lens also differ depending on lens type. Early intraocular lenses were formed of hard materials such as plastics or glass. Polymethylmethacrylate was and still is a very common plastic material of which intraocular lenses are fabricated. These hard lenses conventionally included attaching or centering appendages called haptics, which are shaped as loops or hooks and made of thin resilient material. Materials now in use for haptics include polymethylmethacrylate (PMMA), polypropylene and polyimide. Haptics can be compressed during implantation such that the incision necessary to insert the lens into the eye can be minimized. After the lens passes through the surgical opening, the haptics expand to their memory shape to bear on preselected portions of the interior surfaces of the eye and provide proper location and orientation of the artificial lens.

The structure of the eye with respect of the crystalline lens and its implanted supplements or replacements is divided by the iris into two "chambers", iris and the anterior and the posterior. The anterior chamber is situated in front of the iris and the posterior chamber is situated behind the iris and, in front of the natural lens. The intraocular lens may

be placed in either the anterior or the posterior chamber and the structure of the lens varies to accommodate placement and orientation to the selected chamber.

The modern history of intraocular lens implantation commenced in 1949 when Harold Ridley was credited with insertion of the first such artificial lens. The early Ridley philosophy was for placement of the lens in the posterior chamber in general proximity to the space occupied by the extracted lens. Difficulties with the success of the surgical procedure led to the development of an anterior chamber lens (credited to Peter Choyce) and its success led a wave of development of anterior chamber intraocular lenses and related surgical techniques. Many of the lenses featured thin, spring-like metal loops or hooks (haptics) which, when the lens was implanted, rested in the anterior chamber. Difficulty with dislocation led to the inclusion of haptic means that functioned in conjunction with the iris, sometimes including haptics which extended into the posterior chamber. Lenses were also adapted to be sutured into place to overcome the problem with dislocation. Other anterior chamber lenses included "plate" haptics, being supporting appendages extending superiorly and inferiorly from the lens and including "feet" or other means to contact the anterior chamber periphery adjacent the iris to provide support and fixation for the lens. These plate haptic lenses tended to be less flexible and more difficult to implant and did not readily adapt to varying dimensions of different eyes.

With the attendant difficulties with placement and dislocation of the anterior chamber intraocular lens, the posterior chamber has now become a common choice for the intraocular lens. Advances in both the surgical technique and instrumentation have brought the implantation of artificial lenses into the eye to be a routine procedure. It is usual that such lenses are implanted on an "out-patient" basis in a hospital or clinic "one-day" surgery center. Given the limited surgical procedure and shortened recovery time, the phakic use of lenses to supplement the function of the natural lens is becoming more common. People with extreme myopia or hyperopia now have an alternative to thick spectacles. Those individuals who experience difficulties with contact lenses may also be candidates for phakic corrective lenses.

Aided by the development of surgical techniques relating to anterior capsulotomy, it is now possible to routinely remove the natural lens, leaving intact the capsular bag having

the elastic posterior capsular bag, anterior capsular rim portion around the capsulotomy, including the sulcus formed by the capsular bag attached around the ciliary muscle of the eye. On entering the anterior chamber, the natural lens is conventionally removed by phacoemulsification and aspiration. The intraocular lens is then implanted into the posterior chamber through the capsulotomy. The remaining capsular rim, being a remnant of the anterior portion of the capsular bag after the capsulotomy, and the iris define between them a region known as the ciliary sulcus. This circular groove of the ciliary sulcus provides a convenient situs for the placement and orientation of an intraocular lens, being in the region first identified by Ridley, and generally in the area vacated by the extraction of the natural lens. Likewise, the anterior capsular rim and the posterior capsular bag also provide a favorable circular groove for the placement of an intraocular lens; however, it should be recognized that this groove has a somewhat smaller diameter than the ciliary sulcus. Placing a lens in this region of the anterior rim and posterior capsular bag is known as putting the lens "in the bag".

Advances in surgical technique and instrumentation have fostered development of lenses that may be inserted through smaller incisions. Design advances responding to this stimulus are foldable haptics made of such materials as polypropylene, polyimide, PMMA, and lenses of flexible materials such as silicone, hydrogels, hydroxymethylmethacrylate, polyesters, collagen copolymers and acrylics which may be folded, rolled or otherwise reduced across their width to be inserted through an incision smaller than the optical diameter of the lens.

In placement of an aphakic intraocular lens in the capsular bag in order to place the artificial lens in a location most closely approximating that of the natural lens, it is not uncommon that the lens is ultimately placed into the ciliary sulcus. While such placement is also a suitable situs for implantation, it should be appreciated that the chamber defined by the ciliary sulcus is somewhat larger than that provided by the capsular bag. Accordingly, it is important that the haptics on such lenses have the capacity to accommodate to the size of the chamber into which they are implanted.

Likewise, current surgical technique prefers a lens which may be substantially reduced in one dimension during implantation so as to enable implantation through the smallest

incision possible. Lenses have been developed which may be folded or rolled for implantation to provide such a small aspect on implantation. U. S. Patents Numbers 4,673,406; 4,463,457; 4,490,860; 4,573,998; 4,704,123; and 4,769,035 are illustrative of intraocular lenses fabricated of soft, foldable materials. Additionally, surgical instruments have been developed which facilitate the folding and inserting the lens through the incision. U. S. Patents Numbers 4,934,363; and 5,474,562, assigned to the assignee of the present invention, illustrate such devices.

With the resurgence of interest in implanting lenses into the posterior chamber of the eye, there has been a concomitant resurgent interest in intraocular lenses having haptics of the type frequently included on anterior chamber intraocular lenses. The previously mentioned lens patents illustrate plate haptics on lenses and U.S. Patents Numbers 4,409,690 and 4,403,353 illustrate intraocular lenses having haptics analogous to plate haptics, on lenses adapted for implantation into the anterior chamber. Plate haptics are generally preferred for posterior lenses since the resilient, filament-like, open and closed loop haptics are difficult to control during implantation and, if released untimely in the implantation process, may cause damage to the interior of the eye. Long term stability of lenses with open and closed loop haptics has also been recognized as a problem. Whether of an open or closed loop configuration, these filament haptics provided only limited tension against the eye chamber into which implanted on the short term and when fibrous tissue enveloped the haptic, the optic was often displaced from the implanted position. With the continued development of flexible materials, it became possible for both aphakic and phakic intraocular flexible lenses to be adapted with flexible plate haptics which were more easily inserted to contact the inner chamber into which the lens was implanted, to acquire the secure location and orientation necessary for a successful experience with the artificial lens. The flexible plate haptic seemed to also offer added security to the placement of the lens, being less subject to distortion by fibrous ingrowth of tissue at the contact site.

Further refinement in haptic design was necessitated by the uncertain location of a posterior chamber lens implanted after capsulotomy, (i.e., in the bag or in the ciliary sulcus). This refinement was made by adding filament-like loop haptics to the plate haptics. Alternatively, the plate haptic may be hinged, commonly adjacent the optic and occasionally

also near the support surface. However, the inclusion of these loop haptics extending from plate haptics resulted in the same disadvantages as the filament-like loops extending directly from the optic in anterior chamber lenses. It is known that these spring loaded tensioning loops may permit the optic to shift its location in the posterior chamber. While providing some short term fixation, over time, whether by the action of fibrosis of the adjacent tissues or a shifting or fatigue of components of the lens, if the lens does not receive secure continued support from the haptics, the lens tends to assume a Z-shape (in cross section) with the optic shifting nearer to the iris. This instability renders the power/focal point of the lens to be misaligned for the new location assumed by it and may necessitate spectacles or contact lenses to correct the vision.

The lens of the present invention addresses these prior shortcomings by providing an aphakic or a phakic posterior chamber lens having good short and long term stability whether placed in the capsular bag or in the ciliary sulcus.

It is an object of the present invention to provide an intraocular lens with support structure that is suitable for aphakic lens implantation in either the ciliary sulcus or the capsular bag following the removal of the natural crystalline lens of the eye such as through capsulorhexis.

It is an alternative object of the present invention to provide an intraocular lens and support structure that is suitable for phakic lens implantation in the ciliary sulcus anterior to the natural lens.

It is a further object of the present invention to provide an intraocular lens for implantation in the posterior chamber of the eye which provides sufficient stability of the lens in position and orientation when implanted that it retains its relative position in the posterior chamber during the implant's history.

According to one embodiment of the invention, a foldable intraocular lens is described which includes a support member of a foldable material adapted to be seated directly in the ciliary sulcus or the capsular bag providing sufficient contact with the posterior chamber for short term fixation and including means for fibrous tissue ingrowth for long term fixation.

Additional features of the present invention include a support member having included therein a spring loop haptic to ensure immediate tension fixation in the posterior chamber of the eye should additional fixing tension be necessary on implantation to ensure initial fixation of the lens from the spring loop in the posterior chamber of the eye, wherein the spring loop has the capability to be deflected into a receiving recess in the support member.

Figure 1 is the anterior view of the of one embodiment of the intraocular lens according to the present invention.

Figure 2 is a sectional view of the lens of Figure 1, taken on line 2-2 in Figure 1.

Figure 3 is a section through a human eye from which the matrix of the natural lens has been removed by a surgical procedure such as capsulorhexis of the natural lens, and further illustrating the implantation of the intraocular lens according to the present invention into the ciliary sulcus.

Figure 4 is a sectional view of the human eye similar to Figure 3 however illustrating the implantation of the intraocular lens according to the present invention within the remaining capsular bag after capsulorhexis.

Figure 5 is the anterior view of an alternative embodiment of the intraocular lens illustrated in Figure 1 wherein the optic is oval and includes alternative spring loops.

Figure 6 is the anterior view of an alternative embodiment of the intraocular lens illustrated in Figure 1 wherein the spring loops are mounted centrally in the upper support member.

Figure 7 is the anterior view of an alternative embodiment of the intraocular lens illustrated in Figure 1 wherein the spring loop is affixed at opposite corners of the upper support member.

Figure 8 is the anterior view of an alternative embodiment of the intraocular lens illustrated in Figure 1 wherein the optic and support members are concentrically circular.

Figure 9 is the anterior view of an alternative embodiment of the intraocular lens illustrated in Figure 1 wherein the lens is of single piece construction.

Figure 10 is a sectional view of the human eye including the natural crystalline lens illustrating the phakic implantation of an alternative embodiment of the present invention.



Figure 11 is a sectional view of the lens of Figure 2, illustrating a concave-convex alternative embodiment of the lens.

Figure 12 is a sectional view of the lens of Figure 2, illustrating a bi-convex alternative embodiment of the lens.

Figure 13 is a sectional view of the lens of Figure 2, illustrating a bi-concave embodiment of the lens.

Figure 14 is a sectional view of the lens of Figure 2, illustrating a concave-plano alternative embodiment of the lens.

Figure 15 is a sectional view of the lens of Figure 2, illustrating a convex-plano alternative embodiment of the lens.

Figure 16 is a sectional view of the lens of Figure 2, illustrating a plano-concave alternative embodiment of the lens.

Figure 17 is a sectional view of the lens of Figure 2, illustrating a plano-convex alternative embodiment of the lens.

Turning now to the drawings and to Figures 1 and 2 in particular, an embodiment of the present invention is illustrated. The intraocular lens 2 includes an optic 4 on opposite sides of which are disposed upper and lower support members, 6 and 8, respectively. Upper and lower support members 6 and 8 are somewhat trapezoidal in shape and are attached to optic 4 at its periphery generally throughout their common arcs with the optic. In the context used herein, "trapezoidal" includes the shape of support member 6 and 8 wherein their opposite sides may also be parallel, thus forming a rectangular shape. Upper haptic 6 terminates in an edge 20 and includes lands 10 or thickened portions illustrated as raised portions, disposed at the distal corners 12 and 12' from optic 4. The distal periphery of upper haptic 6, between corners 12 and 12', has formed therein recess 14 within which spring loop 16 is disposed, being attached to upper haptic 6 at one of the corners 12. Hole 18 is disposed in the unattached end of spring haptic 16, opposite the point of fixation at corner 12 and generally adjacent corner 12'. Lower support member 8, also of a somewhat trapezoidal shape extending radially from optic 4, terminates in a distal edge 20 and has disposed adjacent thereto anchor hole 22, being symmetrically spaced between corners 12, 12'. While a single anchor hole is illustrated, it is considered within the scope of the present to include

additional holes, should such be desirable. Optic 4 is an optical lens having an anterior lens surface 24 and posterior lens surface 26, which is better viewed in Figure 2.

In a preferred embodiment, intraocular lens 2 is formed of a single, soft or foldable material, known in the art as a "one piece lens". In the one piece lens, optic 4 support members 6 and 8 and spring loop 16 are all formed integrally and of a single material. Single piece intraocular lenses such as lens 2 are commonly made of silicone, hydroxyls such as hydroxyethylmethacrylate (HEMA), hydrogels, polyesters, collagen copolymers and soft acrylics. By manufacturing intraocular lenses of such soft, foldable materials, the lens may be rolled or folded prior to insertion into the eye such that the lens which otherwise may extend some 4 to 8 millimeters in width and perhaps up to 14 millimeters in length, may be inserted through an incision of approximately 4 millimeters or less in length. Facilitating such implantation of a folded, soft intraocular lens is an insertion device such as The *Passport*<sup>TM</sup> Foldable Lens Placement System manufactured and sold by the assignee of the present invention.

While it is common that such soft, foldable lenses are manufactured of a single material, the present invention is not so limited. The lens 2 of the present invention may also be fabricated with component support members and/or spring loops haptics of a similar or differing material than the optic wherein the spring loops, by way of example, are fabricated of materials such as a polypropylene polymethylmethacrylate, polyimide or the like. These flexible haptics are "welded", attached with an adhesive, molded or staked, according to procedures known in the art. In fabricating an intraocular lens capable of folded insertion yet having the structural integrity to seat securely within the appropriate chamber of the eye, combinations of materials are frequently used for various parts of the intraocular lens to provide the requisite short and long term stability of the intraocular lens.

While in the preferred embodiments, the lens 2 may be formed of any of the flexible optic materials to obtain the advantages of the good optical, light transmitting properties of such materials, we have found it advantageous to use a resilient material for the fabrication of filament-like spring loops; one which provides excellent memory and flexibility such that it may be bent during insertion but has sufficient resilience to firmly retain the lens in place when initially implanted. In the present invention, upper support member 6 and lower

support member 8 may be advantageously formed of silicone integrally with optic 4 and depending from the periphery of the optic 4. The lens 2 of the illustrated embodiment of the present invention additionally includes a spring loop 16 attached to the upper support member 6. This loop 16 may be fabricated of the same material as the haptic, and be integrally molded or cut from the single piece of material from which the optic 4 and support members 6 and 8 are formed. Alternatively, spring loop 16 may be formed of another of the commonly used flexible materials for loop haptics, such as polyimide, polypropylene or PMMA. If a different loop material is selected, the loop 16 is molded or staked into the upper support member generally as illustrated (by dashed line) in corner 12 at 26 (Figure 1). Staking is a process wherein the end of the haptic is fit into a complimentary hole or recess for a secure mechanical fit and wherein one or both of the contiguous materials may be melted to increase the strength of the fit. Upper support member 6 includes spring loop 16 which in the present embodiment is formed of polyimide. Spring loop 16 is molded into upper support member in a manner known in the art, however, including angled hook 28 to provide additional torsional stability of the loop 16 in support member 6.

In the illustrated embodiment upper support member 6 and lower support member 8, adjoin optic 4 at its circumference or periphery and gradually narrow in width toward their distal corners 12, 12' and edge 20. In its illustrated form the optic 4 is circular, being about 6 millimeters in diameter and the support members 6 and 8 narrow to a width of about 4 millimeters at edges 20. While optic 4 is illustrated as circular, it may be of any round, elliptical or oval shape so as to provide the desired optical properties of focusing an image on or about the retina. Optic 4 may be approximately 0.38 millimeters thick (measured maximum thickness between the anterior lens surface 24 and posterior lens surface 25) for a silicone lens of 6 millimeter diameter for a lens of 13 power and 14 millimeter focal length. For the illustrated lens, the thickness of upper support member 6 and lower support member 8 is approximately 0.25 millimeters. The thickness of the upper support member 6 in the region included by the lands 10 is approximately an additional 0.03 millimeters or about 0.28 in total thickness. Lands 10 add additional thickness for strength and stability in this area of the haptic 6, particularly to provide adequate support for spring loop 16 should it be such as polyimide and molded into the silicone support member. The irregular surface of support

member 6 resulting from the inclusion of lands 10 also provides opportunity for additional long term fibrous fixation. The vertical extent of the lens including support members 6 and 8 as viewed in Figure 1, is approximately 12 millimeters. While lands 10 are illustrated only on the upper support member 6, they may also be added to the corners of the lower support member 8.

Lower support member preferably includes anchor hole 22 disposed centrally adjacent the edge 20 of lens 2. Anchor hole 22 has a diameter in the range of about 0.3 to 2 millimeters, being selected to encourage the ingrowth of fibrous tissue into the hole to further stabilize the lower support member 8 in its implanted position. As should be recognized, it is within the scope of the present invention to add additional anchor holes and to vary their diameter or position to enhance the stabilization of lower support member by enhancing the ingrowth of tissue.

Spring loop 16 is illustrated in Figure 1 in its extended position, forming an approximate angle of about 20° with edge 20 (the line formed between corners 12, 12', at their most distal point). Upon implantation, spring loop contacts either the capsular bag or the ciliary sulcus, depending upon the position of implantation in the eye (see Figures 3 and 4) and is depressed according to the degree of contact. Spring loop 16 is illustrated (in dashed form) in a position of complete compression wherein it is received into recess 14 and is essentially tangent to edge 20 extending between the distal portions of corners 12, 12'. Compression of spring loop 16 toward the fully compressed position is effected by the tension against the capsular bag or ciliary sulcus (Figures 3 and 4). Placement of the lens into the capsular bag will result in greater compression of spring loop into recess 14. Land 10 at corner 12' may be adapted with a groove, in a plane parallel with upper support member 6, to facilitate the receipt of spring haptic 16 within recess 14. Spring loop 16 includes anchor hole 22 disposed in the free end of spring loop 16. Anchor hole 22 permits ingrowth of fibrous tissue into and around hole 22 after implantation, providing added security in the placement and orientation of optic 4. Anchor hole 22 also provides the surgeon an added degree of manipulation of the lens 2 on implantation, by providing an attachment point for a surgical instrument should that be advantageous in positioning the lens 2. Upper and lower haptics 6 and 8 are illustrated with each being attached to optic 4 over an extent of

substantially one-half the circumference of the optic 4. It is within the scope of the invention that one or both of the haptics may be of a width so as to subscribe an attachment of less than one-half the circumference of optic 4, but not less than one-fourth thereof.

Referring now to Figures 3 and 4, positioning of lens 2 is illustrated in the two principal locations for implantation of the lens 2. In Figure 3, a simplified diagram of the eye shows the landmark structures relevant to the implantation of an intraocular lens with respect to the present invention. Eye 30 includes the optically clear cornea 32, an opaque sclera 34 adjacent thereto, the retina 36 and the iris 38. Eye 30 in Figure 3 is illustrated in its condition after capsulorhexis has been performed wherein the natural crystalline lens (not shown) has been removed and there remains the posterior capsular bag 40, including the anterior capsular remnant or rim 42 which circumferentially surrounds a central round opening generally behind iris through which the natural lens was removed. The capsular bag 39 is secured about its periphery by fibrous zonules 46 which attach to the ciliary muscle. Anterior to the anterior rim 42 and posterior to iris 38 is a circumferential channel known as the ciliary sulcus 48. It is preferred practice in the implantation of posterior chamber (behind the iris) intraocular lenses to place them either "in the bag" in the region defined by the anterior rim 42 and the posterior capsular bag, or within the ciliary sulcus region. In Figure 3, one embodiment of the present invention, lens 2 is illustrated as implanted into the ciliary sulcus 48, with lower support member 8 snugly received in the lower vertical portion of the ciliary sulcus 48 and upper support member 6, with spring loop somewhat compressed, making contact with the upper vertical portion of the ciliary sulcus 48. In this embodiment, spring loop 16 provides initial positioning and orientation of optic 4 opposite the opening of the iris 38 and in the sight line through optic 4 to the back of the retina 36 (not shown). Anchor hole 22 (Figure 1) is adjacent the fibrous tissue zonules 46 and ingrowth of such tissue into anchor hole 22 provides additional securing of the lens 2 in its preferred orientation. Likewise, lower anchor hole 22 is disposed in the region of the fibrous zonules 46 and tissue ingrowth into anchor hole 22 and around the periphery of lower support member 8 will provide additional securing of lens 2 in its preferred orientation. Corners 12 and 12', recess 14, and spring loop 16 provide advantageous surfaces for fibrous tissue attachment providing additional security of lens 2 in the superior position.

Referring now to Figure 4, lens 2 is illustrated as implanted within the capsular bag 39. It will be observed that lower support member 8 is disposed within the capsular bag 39 at the lower vertical position of the bag 39, intermediate the anterior rim 42 and the posterior bag 40. Upper support member 6 is similarly disposed within the capsular bag 39 however, at the superior vertical position of the bag 39, intermediate the anterior rim 42 and the posterior bag 40. When disposed within the capsular bag, spring loop 16 is more noticeably deflected, as by being displaced into recess 14 (Figure 1) such that the distal corners 12, 12' of the upper support member 6 provide additional support for the positioning and orientation of optic 4. The inclusion of loop anchoring hole 22 and crevices formed by the depression of spring loop into recess 22 invite tissue ingrowth, providing further support for the positioning and orientation of lens 2.

Figures 5 through 9 illustrate alternative embodiments of the present invention wherein the reference numbers are consistent with Figures 1 through 4. Figure 5 illustrates a lens including an oval optic 4 disposed in support member 7, being support members 6 and 8 integrally joined to constitute a single support member. As may be seen, optic 4 is fully disposed within the periphery of support member 7. The illustrated embodiment also includes a pair of spring loops 16, 16', each of which is disposed in upper support member 6 adjacent a corner 12, 12' and projecting toward the opposite corner. Figure 6 illustrates an embodiment of an intraocular lens according to the invention having a pair of spring loops 16, 16' projecting from edge 20, generally centrally in recess 14. Loop 16 projects distally of edge 20 and toward corner 12'. Loop 16' projects distally of edge 20 and toward corner 12. Figure 7 illustrates an alternative embodiment wherein a single spring loop is affixed on each of its ends adjacent corners 12 and 12' however extending adjacent recess 14. Figure 8 illustrates the embodiment of an intraocular lens having circular optic 4 and a circular support member 6, generally concentric with optic 4. Spring loop 16 is disposed in the superior position of support member 6. Figure 9 illustrates an embodiment wherein lens 2 is a single piece lens and support members 6 and 8 and spring loop 16 are integral parts of the lens 2.

In an alternative embodiment (Figure 10), lens 2' is adapted for phakic implantation. In such technique, lens 2' is adapted to be placed into the ciliary sulcus 48, intermediate the

iris 38 and the capsular bag 39, containing the natural lens 50. Figure 10 illustrates the positioning of lens 2' in eye 30 in which the lens surfaces 24 and 25 are adapted to form a convex-concave lens surface and be disposed in front of the natural lens. Figures 12, 13, 14, 15, 16 and 17 illustrate lenses according to the present invention, adapted with bi-convex, bi-concave, concave-plano, convex-plano, plano-concave and plano-convex lens surfaces for treating various refractive errors. Upper and lower support members 6, 8, anchoring holes 18, 22 and spring loop 16 function as described previously in reference to Figure 3 and implantation of lens 2 in the ciliary sulcus 48. These configurations of lenses may also be applicable in an aphakic eye which has undergone clear lensectomy.

It should be appreciated that the foregoing specification and accompanying drawings set forth, by way of illustration and not limitation, the present invention and that various modifications and changes may be made thereto without departing from the spirit and scope of the present invention, which is to be limited solely by the scope of the appended claims.

CLAIMS

What is claimed is:

1. An intraocular lens formed of a foldable material for implantation in either a phakic or an aphakic eye, comprising:
  - (a) an optic portion having a peripheral edge;
  - (b) a support for holding the optic portion in the eye, said support connected to and projecting radially outward from the peripheral edge;
  - (c) the support including at least first and second opposed support members extending a predetermined distance around the peripheral edge, and further extending radially outwardly from the peripheral edge to first and second outer support edges, respectively, said support edges being configured to engage an internal surface of the human eye;
  - (d) one resilient spring loop connected to and projecting radially outwardly from only said first outer support edge and being configured to be movable between an outer position spaced from said first outer support edge and an inner position adjacent the first outer support edge for engaging an internal surface of the eye and effecting immediate support for the lens in the eye; and
  - (e) said second support member including a discontinuity for receiving an ingrowth of human tissue for enhancing long-term fixation of said lens.
2. The intraocular lens of Claim 1 wherein the support surrounds the optic portion.
3. The intraocular lens of Claim 1 wherein the support members have a generally trapezoidal shape with opposite rounded corners.
4. The intraocular lens of Claim 3 wherein each support member extends more than 90 degrees around the peripheral edge.



5. The intraocular lens of Claim 3 wherein each support member extends about 180 degrees around the peripheral edge.
6. The intraocular lens of Claim 1 wherein the optic portion in combination with the support is constructed from a single piece of foldable material.
7. The intraocular lens of Claim 6, wherein the spring loop is formed separately from and connected to the optic portion and support.
8. The intraocular lens of Claim 1 wherein the optic portion in combination with the support and spring loop is constructed from a single piece of foldable material.
9. The intraocular lens of Claim 1, wherein the first support member has a recess portion in the first support edge adjacent the spring loop.
10. The intraocular lens of Claim 9, wherein the spring loop is connected on one side of and extends across the recess portion, the spring loop having a free end spaced from the first support edge.
11. The intraocular lens of Claim 9, wherein the spring loop is connected to both sides of and extends across the recess portion.
12. The intraocular lens of Claim 9, wherein a pair of spring loops are connected to opposite sides of the recess and extend in opposite directions across the recess portion and have free ends spaced from the first support edge.
13. The intraocular lens of Claim 9, wherein a pair of spring loops are connected in the recess portion and extend toward opposite sides of the recess portion and have free ends spaced from the first support edge.

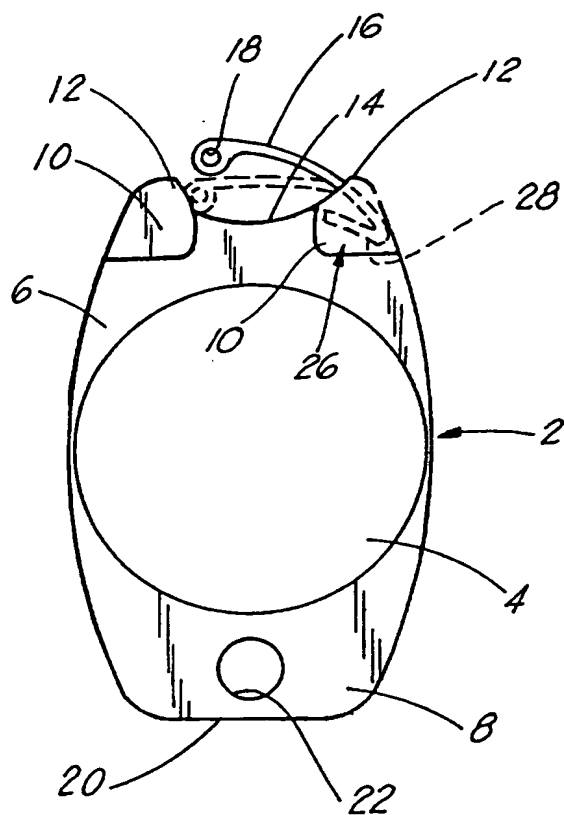
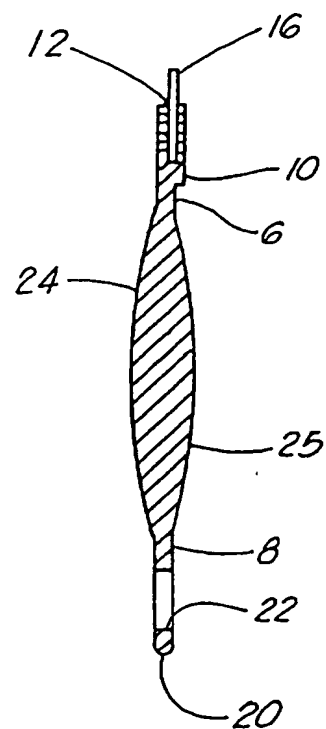
14. The intraocular lens of Claim 1, wherein the first support member has a thickened portion in the vicinity of where the spring loop is connected to the first support member.
15. The intraocular lens of Claim 3, wherein the opposite corners have a thickened portion and the spring loop is connected at one of said thickened corners and the other of said corners thickened portion includes a groove to receive the spring loop when moved adjacent the first support edge.
16. The intraocular lens of Claim 1 wherein the discontinuity in the second support member adjacent the second support edge includes a hole.
17. The intraocular lens of Claim 1 wherein the second support member adjacent the second support edge includes a thickened portion.
18. The intraocular lens of Claim 1 wherein the optic is oval.
19. An intraocular lens according to Claim 1 wherein said lens includes anterior and posterior surfaces which are respectively bi-convex.
20. An intraocular lens according to Claim 1 wherein said lens includes anterior and posterior surfaces which are respectively bi-concave.
21. An intraocular lens according to Claim 1 wherein said lens includes anterior and posterior surfaces which are respectively convex-plano.
22. An intraocular lens according to Claim 1 wherein said lens includes anterior and posterior surfaces which are respectively concave-plano.

23. An intraocular lens according to Claim 1 wherein said lens includes anterior and posterior surfaces which are respectively convex-concave.

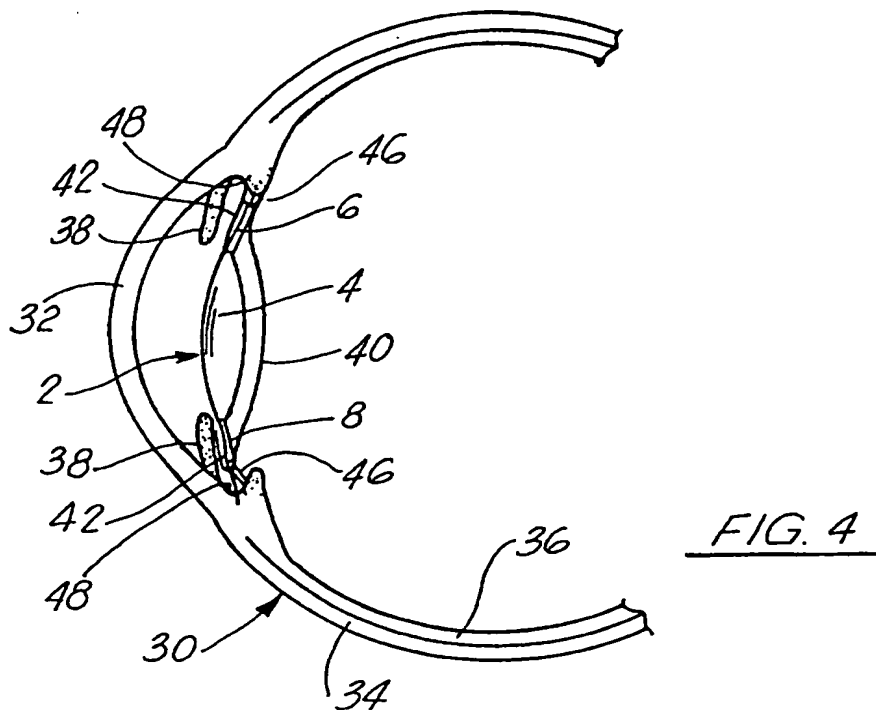
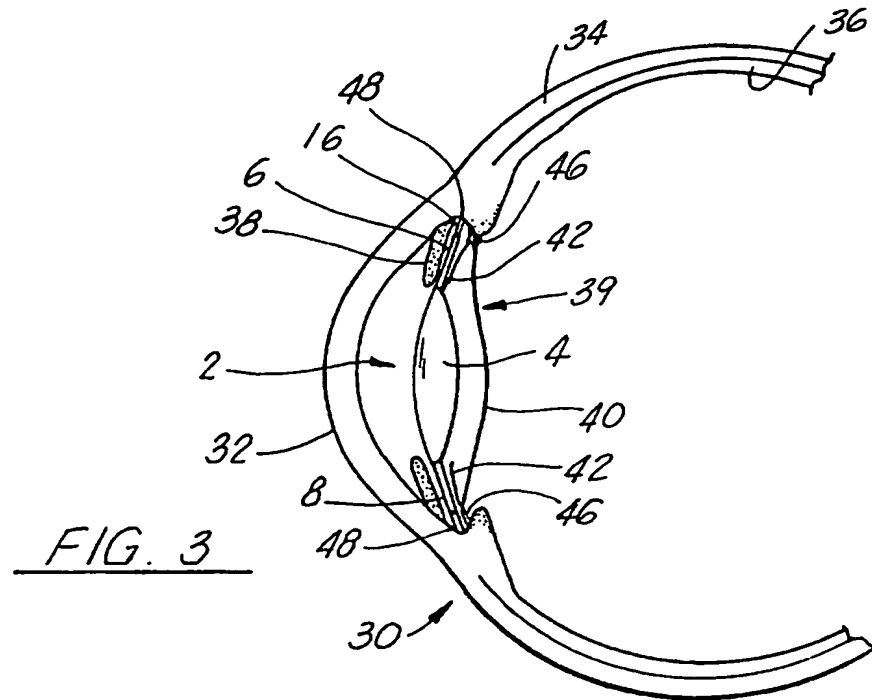
24. An intraocular lens according to Claim 1 wherein said lens includes anterior and posterior surfaces which are respectively plano-convex.

25. An intraocular lens according to Claim 1 wherein said lens includes anterior and posterior surfaces which are respectively plano-concave.

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FIG. 1FIG. 2

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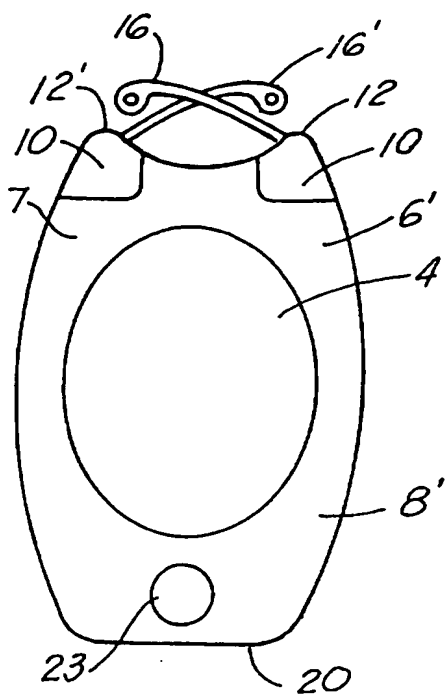


FIG. 5

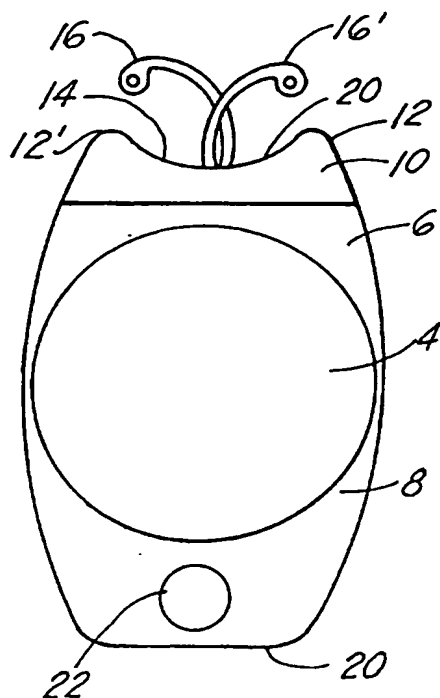


FIG. 6

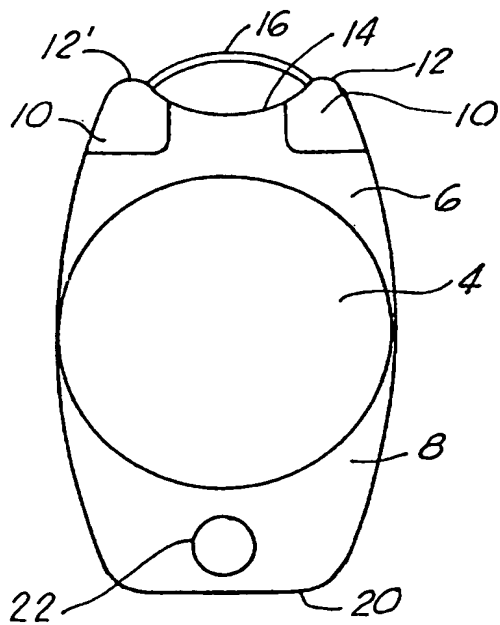


FIG. 7

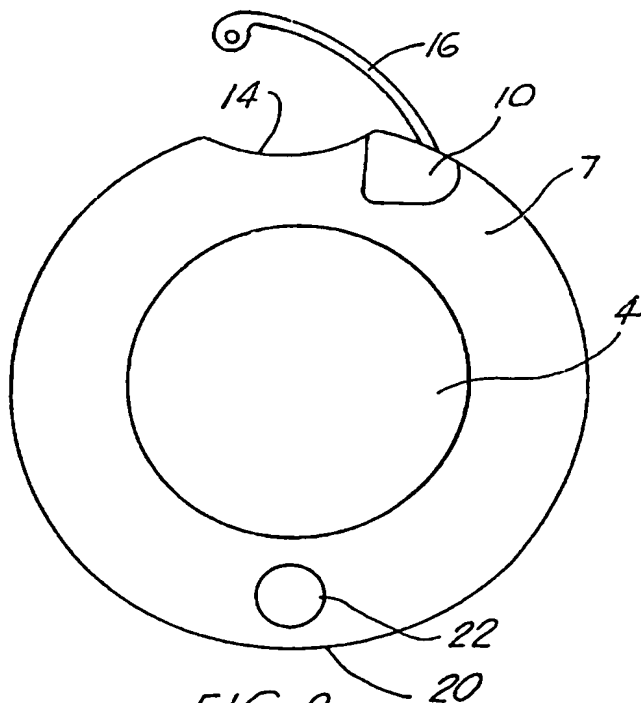


FIG. 8



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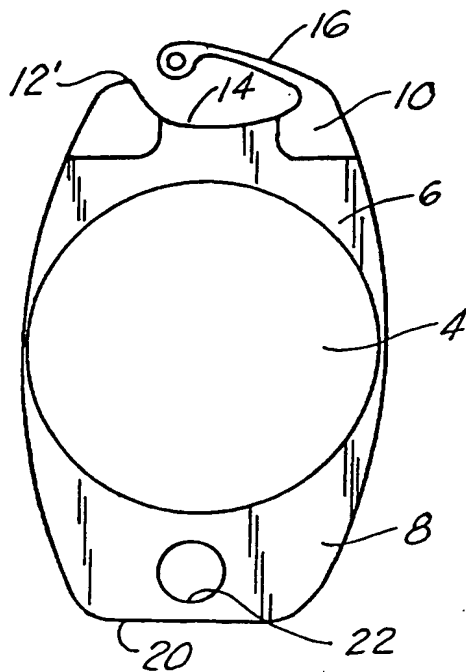


FIG. 9

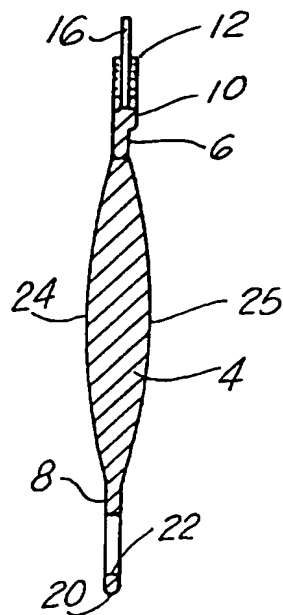


FIG. 12

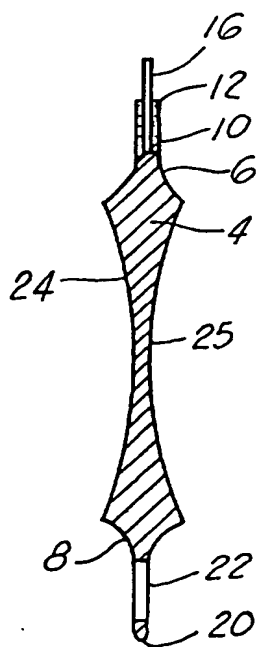


FIG. 13

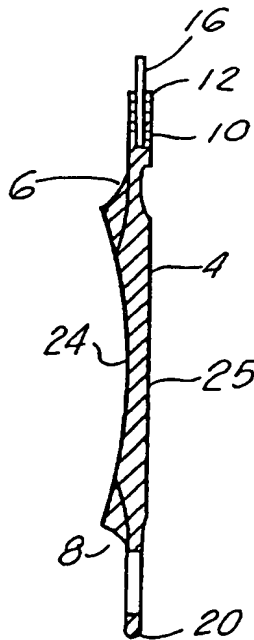


FIG. 14

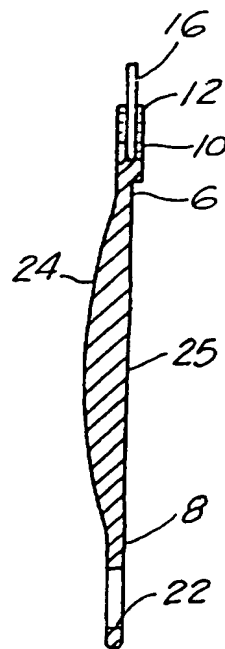


FIG. 15



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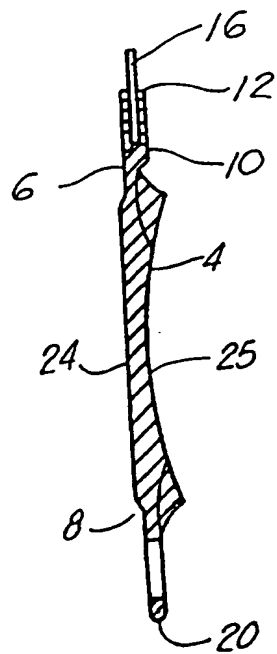


FIG. 16

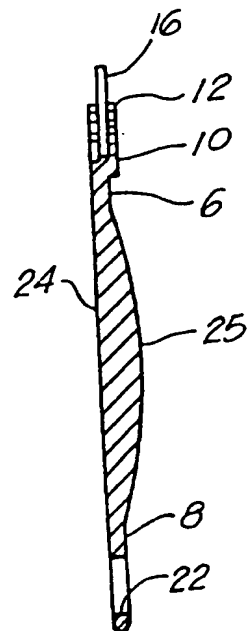


FIG. 17

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US97/13209

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61F 2/16

US CL : 623/6

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/6

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No. |
|-----------|---|-----------------------|
| X         | US 5,047,051 A (CUMMING) 10 September 1991, col. 2, lines 29-36 and 45-56; col. 3, lines 4-14; col. 4, lines 19-22, 33-36 and 64-68; col. 5, lines 12-17; and Fig. 3. | 1-10, 14-17           |
| Y         | US 5,476,514 A (CUMMING) 19 December 1995, Figs. 18 and 21.   | 11-13                 |
| Y         | US, 5,266,241 A (PAREKH) 30 November 1993, col. 3, lines 36-41.   | 18, 19, 24            |
| Y         | US 4,737,322 A (BRUNS et al) 12 April 1988, col. 4, lines 28-33; and Figs. 4-7 and 9.   | 20-23, 25             |

☐ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

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| Date of the actual completion of the international search<br>29 AUGUST 1997   | Date of mailing of the international search report<br>12 SEP 1997                        |
| Name and mailing address of the ISA/US<br>Commissioner of Patents and Trademarks<br>Box PCT<br>Washington, D.C. 20231<br>Facsimile No. (703) 305-3230 | Authorized officer <i>Diane Smith for</i><br>TRAM NGUYEN<br>Telephone No. (703) 308-0804 |